In re: John Colyer

Application No.: 10/597,015

Filed: July 6, 2006

Page 7 of 9

REMARKS

This Response is submitted in reply to the Office Action dated July 17, 2008 (hereinafter, "the Office Action"). In the Office Action, the claims were restricted as follows:

Group I: Claims 1, 30 and 57, drawn to a non-natural presentation system.

Group II: Claim 28, drawn to a product for quantifying the amount of target

moiety, with special technical feature of plurality of presentation and

with different molecular weight of the presentation system.

Group III: Claims 31-52, 54 and 56, drawn to a method of quantifying the amount

of target moiety, with special technical feature of carrying out a separation technique on the presentation system and generate at least

one comparison point of signal intensity produced by said presentation

system.

In response, Applicant hereby provisionally elects Group I corresponding to Claims 1, 30 and 57. Applicant respectfully disagrees with the characterization of WO 98/44350 to Blau et al. (hereinafter, "Blau et al."), and Applicant respectfully submits that it would not be a serious burden to examine Claims 1, 28, 31-52, 54, 56 and 57, or at a minimum, to examine Claims 1, 28, 30 and 57.

Referring to Blau et al., contrary to the assertions of the Office Action on page 2, Applicant respectfully submits that Blau et al. does not teach the presentation system recited in the claims of the present application. Instead, Blau et al. describes a reporter system for monitoring in real time the protein-protein interactions based upon <u>a pair</u> of reporter constructs including a binding moiety and a "crippled" enzyme moiety. Presumably, interaction between two binding moieties (the parameter being monitored) facilitates interaction between two crippled enzymes which reconstitutes an active enzyme.

It is Applicant's understanding that the rationale for the assertion regarding Blau et al. is that the "crippled enzyme" (reporter subunit in Blau et al.) is analogous to the "presentation system" in the present application and that the Blau et al. "binding moiety" is analogous to the "target moiety" in the present application. However, significant distinctions exist between Blau et al. and the present invention. Blau et al. describes an **active** (not an inert) reporter subunit, which requires interaction with a second reporter subunit (identical or non-identical material) to perform the function described. This interaction is a necessary element of the Blau et al. technology creating the enzyme activity which is measured in the use of the technology. Alternatively, the dimerized complex can exhibit an alternative new

In re: John Colyer

Application No.: 10/597,015

Filed: July 6, 2006

Page 8 of 9

characteristic such as a new conformation – which might be recognized specifically by an antibody or other ligand. *See* Blau et al., page 11, lines 27 and 28.

In contrast, embodiments of the present invention are directed to a presentation system including a distinguishable scaffold and a target moiety. The scaffold material is distinct and does not require any additional scaffold components to be effective.

Additionally, according to Blau et al., the binding partner must also be **fused** to a suitable reporter subunit, capable of interacting with the reporter subunit attached to the target binding moiety. There is no such requirement for the present invention. Some of the notable distinctions are summarized and presented below:

Blau et al.	Present Application
Reporter subunit is active	"Analogous" scaffold subunit is passive
Reporter subunit must oligomerize with	Scaffold subunit does not oligomerize
partners	
Binding occurs at two positions in molecule,	Binding occurs between target moiety and
between binding partner moieties and	binding partner moiety
between reporter subunit moieties	
Both binding partner moieties must be	Target moiety attaches to scaffold subunit.
attached to suitable reporter subunits	

Moreover, Applicant respectfully submits that the Examiner has not demonstrated that the requirements for claim restriction have been met. In particular, it is stated in section 803 of the Manual of Patent Examining Procedure (MPEP) that two criteria for proper restriction of claims must be met: 1) The inventions must be independent and distinct as claimed, and 2) there must be a serious burden on the Examiner if restriction is required. The MPEP further states that "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." In particular, the Examiner has not met the second criterion because there is no evidence provided that it would be a serious burden to examine the claims together. In fact, Applicant asserts that examining all the claims at this time facilitates expeditious handling of this matter.

Accordingly, for at least these reasons presented above, Applicant respectfully requests reconsideration and withdrawal of the restriction requirement to Groups I, II and III, and at a minimum, examination of Claims 1, 28, 30 and 57 during prosecution of the present application. It is Applicant's understanding that withdrawn process claims that depend from

In re: John Colyer

Application No.: 10/597,015

Filed: July 6, 2006

Page 9 of 9

or otherwise include all the recitations of the allowable product claim are to be rejoined. Applicant respectfully submits that this application is now in condition for substantive examination, which action is requested.

In an effort to facilitate efficient prosecution of the present application, in the event that the Examiner is not inclined to exam the application as requested by Applicant,

Applicant's representative respectfully requests a teleconference with the Examiner to discuss the same.

Respectfully submitted,

Shawna Cannon Lemon Registration No. 53,888

Attorney for Applicant

Customer Number 20792

Myers Bigel Sibley & Sajovec, P.A. P.O. Box 37428
Raleigh, NC 27627
919-854-1400
919-854-1401 (Fax)

CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on September 17, 2008.

Betty-Lou Rosser

Date of Signature: September 17, 2008